



1313 North Market Street
P.O. Box 951
Wilmington, DE 19801-0951
302 984 6000
www.potteranderson.com

Bindu A. Palapura
Partner
Attorney at Law
bpalapura@potteranderson.com
302 984-6092 Direct Phone
302 658-1192 Firm Fax

June 22, 2021

VIA ELECTRONIC FILING

The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC-JLH

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle Pharmaceuticals, Inc. (“Eagle”) in the above-captioned matter. We write pursuant to the Court’s May 11, 2020 Oral Order (D.I. 182) as it applies to Eagle’s June 8, 2021 Letter to the Court (D.I. 251) (“June 8 Letter”).¹

Eagle respectfully submits proposed redactions to this letter, along with the supporting Declaration of David Pernock (“Pernock Decl.”). The Pernock Declaration is filed contemporaneously hereto. So that this cover letter can remain public, the accompanying confidential Pernock Declaration explains the sensitive nature of Eagle’s confidential information in the June 8 Letter, and the harm that Eagle will suffer should that information be disclosed to the public. A version of that Letter, highlighted in red to show the specific redactions Eagle seeks, is being filed contemporaneously hereto as Exhibit A.² Eagle explains the bases for its proposed redactions below, as supported by the Pernock Declaration. Eagle

¹ Eagle filed a second letter to the Court on June 8, (D.I. 252), but Eagle does not propose any redactions to that letter. Instead, a public version has been filed contemporaneously, which includes only redactions that have been applied at the request of Amneal’s counsel.

² Exhibit A was filed separately under seal so that this cover letter could be filed publicly. Additionally, Exhibit A includes redactions applied at the request of Amneal’s counsel that pertain to Amneal’s confidential information.

The Honorable Colm F. Connolly

June 22, 2021

Page 2

respectfully requests that the Court allow the portions of the filings that Eagle has proposed to be redacted to remain under seal.

For the Court's convenience, a public version of the June 8 Letter, (D.I. 251), with both Eagle's and Amneal's redactions, is attached hereto as Exhibit B.

* * *

The limited information Eagle seeks to redact is the type of competitively sensitive, proprietary information that Eagle safeguards against disclosure. *See* Pernock Decl. ¶¶ 4–7. In particular, Eagle's proposed redactions are tailored to those portions that disclose confidential information regarding the formulation of Eagle's ANDA Product. Pernock Decl. ¶ 6. Specifically, federal regulations require that the U.S. Food and Drug Administration ("FDA") keep Eagle's ANDA confidential until the application is finally approved. *See* 21 C.F.R. § 314.430. Further, Eagle's business partners that have access to Eagle's ANDA are under a contractual obligation to keep the application and related information confidential. Pernock Decl. ¶ 6.

Courts have recognized that an unapproved ANDA and the information contained therein is "confidential under federal law." *In re Gabapentin Litig.*, 312 F. Supp. 2d 653, 667 n.7 (D.N.J. 2004) (citing 21 C.F.R. § 314.430(b)–(d)); *id.* at 668 (noting that the formulation of a generic drug product is confidential information); *see also Bioavail Labs., Inc. v. Anchen Pharm., Inc.*, 463 F. Supp. 2d 1073, 1083 (C.D. Cal. 2006) (collecting cases discussing confidentiality of the formulation and composition of drug products).

Moreover, as set forth in the accompanying Pernock Declaration, Eagle respectfully submits that public disclosure of the details concerning Eagle's formulation would cause competitive harm to Eagle. *See* Pernock Decl. ¶¶ 7–13; *Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (courts may "deny access to judicial records, for example, where they are sources of business information that might harm a litigant's competitive standing" (citation omitted)).

Eagle is mindful of the Court's desire to permit public access to judicial proceedings, including the public's ability to understand these proceedings. Eagle respectfully submits, however, that the extremely limited nature of the proposed redactions, and the sensitivity of the confidential information set forth in the limited redactions Eagle seeks, weighs in favor of redaction, and allowing Eagle to maintain the confidentiality of this information will not affect the public's ability to understand the proceeding. *See, e.g., Supernus*, slip op. at 8 ("[T]he Court agrees

The Honorable Colm F. Connolly

June 22, 2021

Page 3

with TWi that there is little to no legitimate public interest in the public disclosure of TWi's sensitive information, including . . . the confidential status of its ANDA with the FDA.").

* * *

Eagle respectfully requests that the Court permit these redactions to the public versions of the June 8 Letter (D.I. 251). Counsel for Eagle has conferred with Plaintiff's counsel, and Plaintiff did not raise any opposition to the redactions sought.

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP:nmt/7244461/45185

Enclosures

cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)